UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION
PREVENTION

July 18, 2012

MEMORANDUM

Subject: Efficacy Review for Wildabeast;
EPA Reg. No. 4822-LON;
DP Barcode: 401022

From: Lorilyn M. Montford
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Antimicrobials Division (7510P)

Through: Tajah Blackburn, Team Leader
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7/26/12

To: Marshall Swindell PM33/Zebora Johnson
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Aseptix Research BV
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3632 AX Loenen aan de Vechet, The Netherlands

Formulation from the Label:

Active Ingredient(s)	% by wt.
Hydrogen Peroxide	0.77%
Other Ingredients	99.23%
Total	100.00%

I BACKGROUND

The product, Wildabeast (EPA File Symbol 4822-LON), is a new product. The applicant has requested to register the product for use as a non-food contact sanitizer, and deodorizer for use on hard, non-porous surfaces in household, commercial and industrial facilities. The applicant is referencing efficacy data submitted to support registration of the parent product, All Purpose Cleaner Wipes (EPA File Symbol 89094-E). Studies were conducted at ATS Labs, located at t285 Corporate Center Drive, Suite t t0, in Eagan, MN 55t2t.

This data package contained a letter from the applicant to EPA (dated March t, 20t2), EPA Form 8570-4 (Confidential Statement of Formula), three studies (MRID 48770203 thru 48770205), Statements of No Data Confidentiality Claims for all four studies, and the proposed label.

II USE DIRECTIONS

The product is designed for sanitizing hard, non-porous, non-food contact surfaces, including: appliances (exteriors), bathtubs, bedrooms, bikes, blinds, booster chairs, cabinets, chairs, cribs, counter tops, counters, diaper pails, doorknobs, drawers, exercise equipment, fixtures, floors, garbage cans, laundry hampers, piano keys, shelves, shower doors, showers, sinks, tables, telephones, toilets, vanity tops, tubs, and walls. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: chrome, fiberglass, formica®, glazed ceramic, glass, plastic, porcelain, stainless steel, synthetic marble, stone, vinyl (tile), and rubber. Directions on the proposed label provide the following information regarding preparation and use of the product as a sanitizer: Wipe surface until completely wet. Allow surface to remain wet for 30 seconds. Let air dry. For heavily soiled areas, precleaning is required. Rinse with potable water for food contact surfaces.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Sanitizers (For Non-Food Contact Surfaces)

The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or t5038). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

There are cases where an applicant requests to make claims of effectiveness against additional microorganisms for a product that is to be used as a sanitizer for non-food contact surfaces. The DIS/TSS standards are silent on this matter. Confirmatory test standards would apply. Therefore, 2 product samples, representing 2 different product lots, should be tested against each additional microorganism. Results must

show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes. Furthermore, according to information provided in Section 12.3.2 of ASTM Method E1153-94, which is a test method for the efficacy of sanitizers for non-food contact surfaces, "an average of at least 7.5×10^5 organisms must have survived on the inoculated control squares for the test to be valid."

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 487702-03 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Pre-Saturated Towelette Application)," Test Organism: *Klebsiella pneumoniae* (ATCC 4352) and *Staphylococcus aureus* (ATCC 6538), for All Purpose Wipe, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – February 2, 2012. Project Number A12565.

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352), and *Staphylococcus aureus* (ATCC 6538). Three lots (Lot Nos. APCW-A-LCL $\geq$ 60 days old, APCW-UA-LCL1 and APCW-UA-LCL2)) of the product, All Purpose Wipe, were tested. The laboratory report referenced the Sanitizer Test from DIS/TSS-10 and the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (ASTM E1153). The product was received ready-to-use, as a wipe. The product was not tested in the presence of a 5% organic soil load. Five sterile glass carriers (1 inch x 1 inch) per product lot were inoculated with 20.0 µL of a 48-54 hour old suspension of test organism. The inoculum was spread to within ~1/8 inch of the edges of each carrier. The carriers were dried for 20 minutes at 35-37°C at 40% humidity. Following completion of drying, each carrier was wiped with the saturated towelette according to the sponsor specified wiping procedure. Each inoculated carrier was treated with the towelette by passing back and forth twice for a total of 4 passes using staggered intervals. Treated carriers were held for a 30 second exposure time at 20°C and a relative humidity of 20%. Within 30 minutes of neutralization, for *S. aureus*, duplicate 1.00 mL aliquots of the neutralized solution (10^0) and duplicate 1.00 mL aliquots of a ten-fold serial dilution (10^{-1}) were plated onto the recovery agar plate medium. For *K. pneumoniae*, duplicate 1.00 mL and 0.100 mL aliquots of the neutralized solution (10^0), were plated onto the recovery agar plate medium. Plates were incubated at 35-37°C for 48 ±4 hours. Following incubation, the subcultures were visually enumerated. Representative test plates showing growth were stained or/or biochemically assayed to confirm or rule out the presence of the test organism.

Note: Confidential Statement of Formula (CSF) contains a note to the reviewer addressing the tested active ingredient concentration.

2. MRID 487702-04 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Pre-Saturated Towelette Application)," Test Organism: *Streptococcus pyogenes* (ATCC 19615), for All Purpose Wipe, by Nicole Albert. Study conducted at ATS Labs. Study completion date – February 17, 2012. Project Number A12685.

This study was conducted against *Streptococcus pyogenes* (ATCC 19615). Two lots (Lot Nos.APCW-UA-LCL1 and APCW-UA-LCL2) of the product, All Purpose Wipe, were tested. The laboratory report referenced the Sanitizer Test from DIS/TSS-10 and the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (ASTM E1153). The product was received ready-to-use, as a wipe. The product was not tested in the presence of a 5% organic soil load. Five sterile glass carriers (1 inch x t inch) per product lot were inoculated with 20.0 µL of a 48±4 hour old suspension of test organism. The inoculum was spread to within ~1/8 inch of the edges of each carrier. The carriers were dried for 20 minutes at 25-30°C at 73% humidity. Following completion of drying, each of the five carriers were wiped with the saturated towelette according to the sponsor specified wiping procedure. Each inoculated carrier was treated with the towelette by passing back and forth twice for a total of 4 passes using staggered intervals. The carriers were allowed to expose at 2t°C and 18% relative humidity for 30 seconds. Following exposure, each carrier was transferred to 20 mL of neutralizer using identical staggered intervals. The carriers were vortex-mixed. The plates were incubated for 48±4 hours at 35-37°C in CO_2. The subcultures were placed at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were visually enumerated.

Note: Confidential Statement of Formula (CSF) contains a note to the reviewer addressing the tested active ingredient concentration.

3. MRID 487702-05 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Pre-Saturated Towelette Application)," Test Organism: *Escherichia coli* O157:H7 (ATCC 35150), for All Purpose Wipe, by Nicole Albert. Study conducted at ATS Labs. Study completion date – February 17, 2012. Project Number A12684.

This study was conducted against *Escherichia coli* O157:H7 (ATCC 35150). Two lots (Lot Nos.APCW-UA-LCL1 and APCW-UA-LCL2) of the product, All Purpose Wipe, were tested. The laboratory report referenced the Sanitizer Test from DIS/TSS-10 and the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (ASTM E1153). The product was received ready-to-use, as a wipe. The product was not tested in the presence of a 5% organic soil load. Five sterile glass carriers (1 inch x 1 inch) per product lot were inoculated with 20.0 µL of a 48-54 hour old suspension of test organism. The inoculum was spread to within ~1/8 inch of the edges of each carrier. The carriers were dried for 20 minutes at 35-37°C at 40% humidity. Following completion of drying, each of the five carriers were wiped with the saturated towelette according to the sponsor specified wiping procedure. Each inoculated carrier was treated with the towelette by passing back and forth twice for a total of 4 passes using staggered intervals. The carriers were allowed to expose at 20°C and 15% relative humidity for 30 seconds. Following exposure, each carrier was transferred to 20 mL of neutralizer using identical staggered intervals. The carriers were vortex-mixed. The plates were incubated for 48±4 hours at 35-37°C. The subcultures were placed at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were visually enumerated.

Note: Confidential Statement of Formula (CSF) contains a note to the reviewer addressing the tested active ingredient concentration.

V RESULTS

MRID Number	Organism	Lot No.	Total No. Surviving (CFU/carrier)	Parallel Control (CFU/carrier)	Percent Reduction
487702-03	*Klebsiella pneumonia*	LCL	$<1.17 \times 10^2$	1.66×10^7	>99.9
		LCL1	$<2 \times 10^1$	1.66×10^7	>99.9
		LCL2	$<2 \times 10^1$	1.66×10^7	>99.9
	Staphylococcus aureus	LCL	$<2 \times 10^1$	9.55×10^6	>99.9
		LCL1	$<2 \times 10^1$	9.55×10^6	>99.9
		LCL2	$<2 \times 10^1$	9.55×10^6	>99.9
487702-04	*Streptococcus pyogenes*	LCL1	$<2 \times 10^1$	4.07×10^6	>99.9
		LCL2	$<2 \times 10^1$	4.07×10^6	>99.9
487702-05	*Escherichia coli* O157:H7	LCL1	$<2.00 \times 10^1$	1.10×10^7	>99.9
		LCL2	$<2.00 \times 10^1$	1.10×10^7	>99.9

VI CONCLUSIONS

1. The submitted efficacy data support the use of the product, Wildabeast, as a sanitizer against the following microorganisms on pre-cleaned, hard, non-porous, non-food contact surfaces for a 30-second contact time with no organic soil load:

Klebsiella pneumonia	MRID 487702-03
Staphylococcus aureus	MRID 487702-03
Streptococcus pyogenes	MRID 487702-04
Escherichia coli O157:H7	MRID 487702-05

Bacterial reductions of at least 99.9 percent over the parallel control were observed within 30 seconds. The parallel control demonstrated an average of at least 7.5×10^5 surviving organisms, which is the criterion set forth in ASTM 1153. Neutralization confirmation testing met the acceptance criterion of growth within 1 $\log_{10}$ of the numbers control. Purity controls were reported as pure. Sterility controls did not show growth.

VII RECOMMENDATIONS

1. The proposed label claims that the product, Wildabeast, is an effective sanitizer against the following microorganisms on pre-cleaned, hard, non-porous, non-food contact surfaces for a 30 second contact time:

Klebsiella pneumonia
Staphylococcus aureus
Streptococcus pyogenes
Escherichia coli O157:H7

These claims are acceptable as they are supported by the submitted data.

2. The proposed label states that the product can be used as a deodorizer. The label must be revised to provide adequate dosage recommendations and complete directions for use of the product as a deodorizer.

3. The following revisions to the proposed label are recommended:

- On page 1 of the proposed label, pounds and ounces should be substituted for ounces and gallons relating to the weight of the product.
- On page 2 of the proposed label, please include the phrase, "use as many wipes as necessary in order to keep the surface wet for the entire contact time".
- On page 2 of the proposed label, remove the statement "Rinse with potable for food-contact surfaces" in the sanitization use direction section is unacceptable. These use instructions imply that the product is acceptable for use as a food contact sanitizer.
- Throughout the label, *E. coli* is listed when *E. coli* O157:H7 was the tested bacterium.
- On pages 4-6, the terms "oxygenated", and "will not harm surfaces" are unacceptable, as they imply safety and environmental preference.
- On page 6 of the proposed label, the claims "Cleans almost/nearly/virtually everything in your home", "any hard surface", and "works all over your home" are unacceptable as these claims imply acceptable use on surfaces and sites beyond what is proposed on the label.
- On page 6 of the proposed label, the claim "gently clean almost everything" is unacceptable. This claim implies that product can be used on surfaces/sites beyond those listed and also implies safety and environmental preference.
- On pages 6 and 7 of the proposed label, the claims "Gentle/mild way to sanitize" and "Gentle for your surfaces" are unacceptable as they imply safety and environmental preference.
- On page 7 of the proposed label, "Quick sanitary action" and "fast-acting sanitary" must be removed. The Agency does not have a standard for sanitary, and this term is often confused with sanitization. Should the registrant chose to replace sanitization with sanitary, the claim is still unacceptable due to the use of the terms quick (which requires contact times ≤ 10 seconds) and fast (contact time not yet defined by the Agency).
- On pages 7, 8 and 28 of the proposed label, remove the terms "gentle" and "mild" as they imply safety and environmental preference.
- On page 7 of the proposed label, the claim "Gloves off cleaning and disinfecting" is unacceptable as it implies safety and environmental preference.
- On page 7 of the proposed label, the claim "Active brakes [sic] down dirt & dissolves into oxygen into oxygen and water" is inaccurate and must be removed from the label.
- The comprehensive list of potential use sites (Table 3, pages 8-11) include the following sites that conflict with the use directions/sites and supporting efficacy claims, and should be removed from the proposed label:
    - Stove tops
    - Can openers
    - China
    - Cutting boards

    - Can openers
    - Dish racks
    - Food preparation areas
    - Grills
- On page t2 of the proposed label, use of the term "safe" is unacceptable as it is false or misleading.
- On pages 11-12 of the proposed label, the terms ceramic, cement, fiberglass, porcelain, porcelain enamel, stone, grout, granite, marble, and wood all reflect porous surfaces in the absence of qualifying information. These surfaces must be consistently qualified or removed from the proposed label.
- On page 13 of the proposed label, remove all references to fungistatic claims and any claims including the organism, "*Aspergillus niger* (ATCC 6275). Data have not been provided to support this claim.
- On pages 14-15, claims "Kills % Germs with the power of/scent of/ fragrance name/scent" are false and misleading. Efficacy of the product is not mediate by the fragrances/scents in the product.
- On pages 22-23, use of the terms "deep" and "tough" as descriptors for sanitization are unacceptable as they imply heighten efficacy.
- On page 23 of the proposed label, remove the claim "The same ingredient used for disinfecting cuts and scrapes" as it expands the uses to skin.
- Throughout the proposed label, remove all references and iterations of "biodegradable", "healthy home", "kinder", "friendly", "gloves off", "no gloves needed", and "Fume-Free" as they imply heighten safety and environmental preference.
- Throughout the proposed label, remove all references and iterations of "active oxygen", "chlorine free", "bleach free", "oxidation/oxidizing", "no chlorine", "breaks down into/leaves behind only water and oxygen", "non-chlorine", "elements of water and oxygen(?)", and "accelerated/hi-speed hydrogen peroxide", for pesticidal claims.
- On page 28 of the proposed label, remove the following claim "Quick easy and convenient disinfecting". The Agency has determined that term "quick" pesticidal claims must demonstrate efficacy in ≤10 seconds.
- On page 28 of the proposed label, the registrant must define the statement "Hygiene beyond cleanliness.
- Allergen claims are limited to non-living allergens with the action of cleaning, removing, or reducing.
- Data Matrix does not indicate MRID numbers for submitted studies and *E. coli* should be changed to *E. coli* O t57:H7.
- The applicant needs to make it clear that this product is a wipe product, just as the parent application (All Purpose Wipe – EPA File Symbol 89094-E).